

REMARKS/ARGUMENTS

In this response, claims 1, 13 and 21 have been amended. No claims have been canceled or added. Thus Claims 1-6 and 9-24 remain pending.

Support for the amendments appears throughout the present specification, which teaches that all of the ingredients are non-toxic and safe for use in the presence of food; since the composition can thus come into contact with food which is subsequently consumed, the composition is therefore edible. Furthermore, ingredients such as D-limonene are naturally occurring in edible materials, i.e., citrus rind, while modified naturally occurring ingredients such as polyethoxylated castor oil are also edible.

I. Rejections Under 35 U.S.C. § 103(a) Based upon Dotolo and PEG-castor oil

The Examiner rejected Claims 1-6, 9-11, 13-17, 22, and 23 under 35 U.S.C. § 103(a) as being unpatentable over Dotolo, U.S. Patent No. 4,379,168 ("Dotolo"). Specifically, Examiner states:

Dotolo teaches a composition comprising 20% d-limonene, 4% emulsifier (surfactant), and remainder water (76%). See Example 14. Dotolo teaches that the d-limonene contains a preservative. See column 6 lines 40-43. Dotolo teaches that the composition can repel or kill insects. See column 7 lines 34-43. Dotolo teaches that the composition controls lice. See column 7 lines 3-4. Dotolo teaches a method of applying the composition to house surfaces such as walls and floors and to animals as a topical application. See column 7 lines 5-11. Dotolo teaches that the composition can be made by the simple act of mixing d-limonene, emulsifier, and

remainder water. See claims 34-36. Dotolo teaches that nonionic emulsifiers (surfactants) such as TON X-100 and IGEPAL CO-630 are specifically used in his invention. See column 1 lines 52-68. Dotolo explains that these surfactants contain a number of ethylene oxide (EO) units. See column 1 line 68-column 2 line 3. Dotolo also teaches that his invention is open to other suitable surfactants, which can be nonionic, cationic, anionic and amphoteric type. See column 2 lines 4-10. Dotolo teaches all that is recited in claims except for the invention comprising 1) a polyethoxylated castor oil surfactant and 2) amount (0.01-5%) of preservative. However, in the absence of a showing of unexpected results for the prior art surfactants versus PEG-castor oil, it would be obvious to one having ordinary skill in the art to modify the invention taught by Dotolo to include PEG-castor oil. One would have been expected to do this since Dotolo is open to inclusion of suitable surfactants and since PEG-castor oil contains a number of EO units which are units also contained in the TON X-100 and IGEPAL CO-630 surfactants (note that PEG-castor oil, TON X-100 and IGEPAL CO-630 are non-ionic surfactants). One would have been motivated to do this because all three surfactants are similar in chemical and physical properties and therefore, would have been expected to exhibit a similar function when used in the same capacity. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of preservative to include in the composition. One would have been motivated to do this in order to prevent the composition from being rancid.

Office Action, dated 05/16/2007, at pages 2-3. For the reasons set forth below, Applicant respectfully disagrees.

The Examiner states that "one would have been motivated to do this [modify the invention taught by Dotolo to include PEG-castor oil] because all three surfactants are similar in chemical and physical properties and therefore, would have been expected to exhibit a similar function." However, the chemical/physical properties of the surfactants disclosed in Dotolo (Triton X-100

and IGEPAL CO-630), as described below, do not have similar chemical and physical properties to the surfactant disclosed in the instant invention, PEG-castor oil. Moreover, there is nothing in Dotolo that expressly or implicitly teaches that chemicals with chemical and physical properties similar to polyethoxylated castor oil would be desirable.

The Examiner states that

the applicant does not provide any data showing why the exchange of a simple surfactant, which is not even an active ingredient, would materially affect the activity of the composition. Until Applicant provides a showing demonstrating a difference in the effectiveness of TRITON X-100 and IGEPAL CO-630 versus PEG castor oil, the Examiner maintains that Dotolo makes obvious that many surfactants including the PEG-castor oil instantly claimed are suitable for the invention taught therein.

Office Action, dated 05/16/2007, at pages 4-5.

There is a difference in the effectiveness of TRITON X-100 and IGEPAL CO-630 versus PEG castor oil. First of all, PEG castor oil is highly viscous. In use as an insecticide, the claimed composition is sprayed on the subject insects and completely coats the insects. The high viscosity prevents the insect from moving (because it is too viscous for them to move their legs or wings), thereby allowing the active ingredients to kill the insect. TRITON X-100 and IGEPAL CO-630 and similar surfactants used in prior art insecticides are not viscous, thereby not coating the insects and allowing them to continue to move. This often does not prove effective. Those skilled in the art understand that many insecticides with surfactants other than

PEG castor oil immobilize insects for a short period of time, but then they get up and walk off. But this does not happen with the presently claimed composition because the PEG castor oil does not allow them to get up and walk off, but coats the insect and prevents it from moving, thereby allowing the active ingredients to kill the insect. Nowhere in Dotolo is it mentioned that the surfactant chosen should have a high viscosity to make the insecticide more effective.

Furthermore, the Examiner states

Note that the specification on page 4 defines 'food grade' components as being '(Generally Recognized as Safe)'. This language does not exclude TRITON X-100 and IGEPAL CO-630 taught by Dotolo since it is unclear as to what is meant by a 'food grade' component being "(Generally Recognized as Safe)".

Office Action, dated 05/16/2007, at page 5.

The claimed composition forms an organic insecticide. The ingredients are all edible plant extracts, i.e., they are from a natural source, like the castor bean and orange-peel rind. This allows the composition to be used on or around food. The composition of Dotolo cannot be used around food because it is a non-natural product that is toxic to humans.

"Food Grade" or "Generally Recognized as Safe" are terms used in the relevant art. Attached as Exhibit A is information generated from a database maintained by the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) under an ongoing program known as the Priority-based Assessment of Food Additives (PAFA). PAFA contains

administrative, chemical and toxicological information on over 2000 substances directly added to food, including substances regulated by the U.S. Food and Drug Administration (FDA) as direct, "secondary" direct, and color additives, and Generally Recognized As Safe (GRAS). The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS. As can be seen on page 3 of Exhibit A, castor oil is listed. TRITON X-100 and IGEPAL CO-630 are not listed because they are not GRAS.

Attached as Exhibit B is the "Resource Guide for Organic Insect and Disease Management" (which can be found at http://www.nysaes.cornell.edu/pp/resourceguide/appendix/appendix_e.php). This Resource Guide helps further understand what is meant by "food grade" or GRAS. It states that

"Under FIFRA, any product making a pesticidal claim must be registered with EPA, in order to review products for reasons of human health and environmental safety. Registration is indicated by the presence of an EPA registration number in small print on the label. FIFRA rules generally require that farmers use only pesticides that are approved by EPA, and labeled for the food crop in question.

An exception to this rule exists for products based on certain active ingredients (the "25b list," named for that section of FIFRA), which are considered minimum risk products. These products will not have an EPA registration number, and usually have a statement to the effect that "the manufacturer represents that this product qualifies for exemption from FIFRA."

As can be seen, the first item on the list is Castor Oil. The products on the "25b" are considered "food grade" and are

"Generally Recognized as Safe." The surfactants in Doloto are not on this list because they are toxic to human beings.

The composition of the present invention can be sprayed directly on the human skin, and even ingested without any significant worry of irritation or accidental poisoning. For example, a housewife who encounters an ant on her counter top while cutting vegetables for the evening meal could spray the ant (killing it), as well as the counter top with the presently claimed composition, wipe away the dead ant with a simple paper towel, and then continue with her work. As far as Applicant knows, this would not be possible with prior insecticides using D-limonene.

For clarification, claim 1 has been amended to recite "wherein said composition is non-toxic to and edible by humans and household animals." Claims 13 and 21 have been amended similarly.

At most, Dotolo teaches a composition containing D-limonene that is useful for killing insect pests on small animals, in the kennels of small animals and in household areas which attract insect pests (col. 1, lines 9-11). Dotolo alone clearly does not show or suggest the present invention. Dotolo shows the combination of Triton X-100, a skin irritating emulsifier (the Kodak Laboratory Chemical Catalog No. 51 indicates that Triton X-100 is irritating to the skin and eyes), together with D-limonene and water, to kill ants, fleas, ticks, and other insect pests. Dotolo is not concerned with human

safety issues, it is only concerned with killing bugs - at any cost, including irritation to human skin and accidental poisoning. To the extent that the Dotolo composition is used, any household surface must be cleaned and detoxicated thereafter. Moreover, the Dotolo composition certainly could not be used on the skin of humans due to its irritating characteristics. Dotolo thus teaches the old kind of insecticide, and Dotolo in no way teaches, suggests or implies that the composition can be used (1) as a treatment for lice infestation in humans; (2) as an insecticide that is not harmful to landscaping, particularly rose bushes and ornamentals, indoor plants or the environment; or (3) as an insecticide in food preparation areas, all of which the presently claimed invention is useful for. In fact, none of the compositions taught by Dotolo contain any surfactants or emulsifiers that were selected for their safety. Nor does Dotolo suggest choosing surfactants based on human safety.

The Examiner states that "Dotolo states that any suitable surfactant can be employed in a pesticide composition." Office Action, dated 05/16/2007, at page 4. However, because Dotolo is only concerned with killing bugs and is not concerned with human safety, one skilled in the art would not be led to use PEG-castor oil based on the teachings of Dotolo.

The combination of Dotolo and PEG-castor oil is improper because 1) there is no support for the proposition that TRITON X-100 or IGEPAL CO-630 has similar chemical and physical properties to that of PEG-castor oil and 2) Dotolo does not

describe a need to have an edible "food grade" surfactant that would have motivated one of ordinary skill in the art to combine Dotolo with PEG-castor oil.

In view of the foregoing, Applicant submits that the 35 U.S.C. § 103 rejection be withdrawn. Reconsideration and withdrawal of the rejection are respectfully requested.

II. Rejections under 35 U.S.C. § 103 under Liebman

The Examiner rejected claims 1-3, 6, 7, 9, 11-15, 20, 21, and 24 under 35 U.S.C. § 103(a) as being obvious over Liebman (CA 2060594). Applicant respectfully notes that claim 7 has been previously cancelled and therefore is no longer pending.

Specifically, Examiner states:

Liebman teaches a method of applying a shampoo or lotion composition comprising d-limonene, emulsifiers, (cocoamido propyl betaine, sodium lauryl sulphate, ethyl methacrylate) and water and/or alcohol to human head to contact lice. Liebman teaches that the method is used to prevent lice infestation in human hair and on skin. See page 1, lines 5-8, page 3 lines 5-22, page 6 examples. Liebman teaches generically that emulsifiers can be added to the invention. See page 4 lines 16-19. Liebman also teaches that modifications to the disclosed embodiments can be made without departing from the scope of his invention. See page 9 lines 26-29. Liebman teaches all that is recited in the claims except for the invention comprising 1) a polyethoxylated castor oil and 2) instant amounts/ranges of ingredients: d-limonene, emulsifying agent, and hydrophilic solvent. However, in the absence of showing of unexpected results for the prior art surfactants versus PEG-castor oil, it would have been obvious to one having ordinary skill in the art to modify the invention taught by Liebman to include PEG-castor oil. One would have been expected to do this since Liebman generically teaches the inclusion of

surfactants (emulsifiers) and since Liebman also teaches that modification to the disclosed embodiments can be made without departing from the scope of his invention. With respect to the amount/ranges of ingredients, one having ordinary skill in the art would have been expected to determine the optimum amounts ranges of ingredients. One would have been motivated to do this in order to develop a lotion that would have been effective in killing lice, but yet non-toxic to the animals being treated.

Office Action, dated 12/5/06, at pages 5-6. For the reasons set forth below, Applicant respectfully disagrees.

Each of Claims 1-3, 6, 9, 11-15, 20, 21, and 24 require that the insecticidal compositions contain castor oil and are food-grade and non-toxic. The arguments set forth above with respect to the Dotolo rejection are reiterated herein.

Similarly, Liebman does not disclose - or even suggest the need for - a food grade composition or the use of food grade ingredients. Nor does it teach the need for a highly viscous composition. Liebman does not have any teaching, suggestion, or motivation to modify the invention with a GRAS, food-grade or highly viscous composition.

In view of the foregoing, Applicant submits that the 35 U.S.C. § 103 rejection be withdrawn. Reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejections under 35 U.S.C. § 103(a) over Wilkins, Jr.

The Examiner also rejected Claims 1, 2, 6, 7, 9, 11-15, 17-19, 21, and 24 as obvious over Wilkins Jr., U.S. Patent No.

5,951,992 ("Wilkins"). Applicant respectfully indicates that claim 7 was previously cancelled.

The Examiner states that Wilkins teaches a method of applying a composition comprising 2-10% D-limonene, 1-10% emulsifier, and 80-96% water to crop or plants to control fire ant infestation. However, Examiner also states that Wilkins does not teach PEG-castor oil or the invention comprising the claimed amounts/ranges of D-limonene, emulsifying agent, and hydrophilic solvent. Reconsideration and withdrawal of the rejection are respectfully requested.

The arguments set forth above with respect to the Dotolo rejection are reiterated herein. Wilkins teaches a method of applying a D-limonene composition to control fire ants. The only emulsifier disclosed in Wilkins is MAZCLEAN EP. As with Liebman and Dotolo, Wilkins fails to disclose a highly viscous, edible, GRAS, food-grade insecticidal composition that comprises PEG castor oil. In addition, the Examiner has neither asserted nor presented any evidence suggesting that MAZCLEAN EP is non-toxic to humans. It is not on the "25b" list in Exhibit B nor the GRAS list in Exhibit A.

Because Wilkins does not disclose a food-grade insecticidal composition comprising castor oil, Wilkins does not disclose or render obvious the invention in Claims 1, 2, 6, 9, 11-15, 21, 24, and 25.

In view of the foregoing discussion, Applicant submits that the § 103 rejections are overcome. Thus, Applicant respectfully requests that the 35 U.S.C. § 103 rejections be withdrawn.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance.

Respectfully submitted,

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